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13. ABSTRACT ***(Maximum 200 Words)***

The Breast Health Intervention Evaluation Study will evaluate the relative effectiveness of three different affective approaches to breast health messages--a fear appeal, a positive appeal, and an affectively neutral, cognitive appeal. The three interventions will be structured as three 10-12 minute videotaped presentations targeting 450 African American women residing in three rural communities in Georgia (150/community). Each site will provide the intervention within a 60-minute workshop format. Workshops will be coordinated by a Community Lay Health Worker at each site. Pre-/post-intervention KAP surveys will be administered. Participants will be provided with breast self-examination information and breast screening referral information. A 12-month follow-up will be conducted.

Analysis and development of the videos will be a collaborative effort between Morehouse School of Medicine and Georgia State University. The collaboration of two institutions creates unique strengths that do not currently exist elsewhere in Georgia. Further, working collaboratively will enable us to combine communications theory with public health research practice.

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Introduction

The Breast Health Intervention Evaluation (BRIE) Study will evaluate the relative effectiveness of three different approaches to breast health messages--a fear appeal, a positive affect appeal, and an affectively neutral, cognitive appeal. The three interventions will be structured as three 10-12 minute videotaped presentations targeting 450 African American women residing in three rural communities in Georgia (150/community). Each site will receive all three of the intervention approaches, and be randomly assigned within the site sample. It will be presented within a 60-minute workshop format. Workshops will be coordinated by a Community Lay Health Worker at each site. Pre-/post-intervention KAP surveys will be administered. Participants will be provided with breast self-examination information and breast screening referral information. A 12-month follow-up will be conducted. We will provide referral services to FDA-approved sites for study participants.

Body: Results & Discussion

This section is organized as follows:

I. Status of activities relative to the current period (Year 04)
II. Relevance to the original hypothesis
III. Review of the Statement of Work and proposed plans for Year 05

I. Status of Activities Relative to the Current Period (Year 04)

According to the revised Statement of Work, Months 37-48 (Year 04) involved the following activities:

Month	
COMPLETED	Recruit study participants
COMPLETED	Identify mammography and clinical breast exam sites
COMPLETED	Organize and conduct 5-7 workshops in each target community
COMPLETED	Evaluate data gathered in workshops
IN PROGRESS	Recruit & train graduate student phone interviewers
51-58	Implement 12-month follow-up
59-60	Analyze data and write reports

RECRUIT STUDY PARTICIPANTS - COMPLETED
ORGANIZE and CONDUCT 5-7 WORKSHOPS in EACH TARGET COMMUNITY - COMPLETED
EVALUATE DATA GATHERED in WORKSHOPS - COMPLETED

The delays that we encountered in the initial developmental phase with respect to both the video production and the questionnaire pre-testing adversely impacted implementation phase including both participant recruitment as well as workshop scheduling and conduct. These issues were discussed at length in previous annual reports.

The proposed Study sites are three rural areas located in south Georgia: Waycross, Valdosta, and Americus. Participant recruitment proceeded very slowly in Americus and Valdosta. In Waycross, however, no activity appeared to occur beyond the organizing of the field pre-test. After some investigation, we discovered that the community health worker in Waycross was unable to carry out the recruitment and workshop activities that she agreed to. Her involvement with the Study was terminated, and rather than risk contamination in Waycross by attempting to indentify, train, and place another community health worker, we elected to move the site to Macon and subcontracted with the Executive Director of the Older Americans Council of Middle Georgia to recruit our third cohort and conduct the workshops. The catchment area for the Older Americans Council of Middle Georgia includes 10 rural counties, not adjacent to either Sumter (Americus) or Lowndes (Valdosta) Counties, with large population segments that are within the Study's participant guidelines and are demographically matched to the defined sample profile.

Overall, recruitment of study participants has been very challenging. Traditional marketing approaches (public announcements, posters, announcements in church-related publications and events) proved to be ineffective. Likewise, attempts by the lay health workers to organize participants into workshops of 20-25 persons were also unsuccessful. Therefore more aggressive marketing technique were used, e.g., direct interpersonal recruitment, speaking engagements, contacting women's groups and church-based women's organizations, recruiting activities at senior citizen centers and organizations. In an attempt to maximize participation, lay health workers conducted smaller and more frequent workshops as these were easier to schedule and resulted in the higher levels of involvement. We discovered that the no-show rate correlated positively with the length of lag time between recruitment and attendance at a workshop. We attempted to minimize this by conducting smaller workshops more frequently. Community health workers provided reminder phone calls a day or two before the scheduled workshop, and they changed the workshop locations to accommodate each particular group. All of these efforts were much more labor-intensive that was envisioned. Despite all these efforts, participant recruitment proceeded very slowly.

As completed surveys were delivered, they were reviewed for eligibility, completeness, and measuring the self-rating of risk of getting breast cancer. During early stages of Study implementation, as the review of submitted surveys was done, several inconsistencies were noticed, some of which predicated undertaking selected validation calls to women who had participated in the study. The validation calls were made to women for whom age was changed from outside of the eligible range to within the eligible range, and a different response to age or time since last mammogram on the contact sheet and the survey form. Those women for whom data were incorrect on the survey form were disqualified from the study and their surveys not used. Additional women and surveys were rendered disqualified based on having a large number of

questions for which responses were not recorded, typically more than 12 questions left blank on a single survey or more than 6 questions left blank in either section for which the same questions were asked before and after viewing the video. The number of disqualified surveys further slowed the pace of data collection because the community health workers were required to recruit replacements.

The entire Study sample was specified at 450 participants (150 in each of three communities). Based on rate of qualified surveys returned and expected losses during period before telephone follow-up, we elected to increase the Macon site by 50 for a total of 500 participants. To date, we have recruited 492 subjects into the Study. Of these, 433 have attended a workshop and provided qualified surveys, and the remaining 59 are scheduled to attend a workshop.

RECRUIT & TRAIN GRADUATE STUDENT PHONE INTERVIEWERS
IMPLEMENT 12-MONTH FOLLOW-UP
ANALYZE DATA and WRITE REPORTS

These activities will be carried out in Year 05 (the approved 12-month extension). See below.

II. Relevance to the Original Hypothesis

Because of the implementational delays as discussed briefly above, our dataset is unanalyzable at the current time. Data entry has been carried out concurrently with data collection, however, no interim analyses are planned due to statistical compromise.

The pilot test was not intended for hypothesis testing, but to assure that the protocol under which the workshops would be implemented was adequate. However, as all aspects of the protocol were utilized, data were collected from which preliminary impressions can be drawn. This format appears to be appropriate for increasing the knowledge of participants as to the need for and use of mammography as well as the major risk factors for breast cancer. Additionally, we added a Risk Score to both the pre- and post- test surveys and women viewing different videos had quite different changes in their perceptions of personal risk for breast cancer between the pre- and post surveys. It is plausible that women viewing a single video could not articulate the affective content, due to its almost subliminal impact, although overall responses to explicit questions varies with affective content. This, of course, is the primary hypothesis to be tested at the end of the implementation and analysis phase of this study.

III. Review of the Statement of Work and Proposed Plans for Year 05

COMPLETED	Focus Groups
COMPLETED	Videoscript development
COMPLETED	Videoscript process evaluation
COMPLETED	Videoscript assessment
COMPLETED	Pre-testing of messages
COMPLETED	Lay Health Worker Training Curriculum Development
COMPLETED	Develop Procedures Manual

COMPLETED	Recruit, hire, & train Community Lay Health Worker in each site
COMPLETED	Survey Q'aire Assessment & Modifications
COMPLETED	Pre-testing of Q'aire
COMPLETED	Video Production
COMPLETED	Establish relationships with target communities
COMPLETED	Assess sociodemographics and comparability of communities
COMPLETED	Recruit study participants
COMPLETED	Identify mammography and clinical breast exam sites
COMPLETED	Organize and conduct 5-7 workshops in each target community
COMPLETED	Evaluate data gathered in workshops
IN PROGRESS	Recruit & train graduate student phone interviewers
YEAR 05	Implement 12-month follow-up
YEAR 05	Analyze data and write reports

PLANS FOR YEAR 05 (Months 49 - 60)

As discussed elsewhere in this and in our previous reports, two significant delays impacted the implementational timeline of this Study: (1) delays in the production of the video stimuli, and (2) invalidation of a survey pre-test group. Because of this, we requested and received a 12-month, no cost extension of this Study (Year 04).

Recruitment of study participants and the conduct of the workshops met with several unforeseen challenges and proceeded very slowly. Issues and complications relative to participant recruitment and workshop scheduling were discussed earlier in this report. All completed surveys have been evaluated for conformance with eligibility criteria and have been entered into EpiInfo 6, our data analysis application. Because of the delays in the recruitment and implementation phases of the Study, we requested and received a second 12-month, no cost extension of the Study (Year 05).

We will initiate the follow-up protocol at approximately 6 months after exposure to the intervention. We do not feel that this will compromise the testing of our Study hypotheses because participants will be exposed to the videotaped stimulus for one time only. Message reinforcement and retention are not variables under investigation in this Study. Therefore, we hypothesize that maximum compliance with the message recommendations (i.e., to get a clinical breast exam and to get a mammogram) is most likely to occur very shortly after exposure to the stimulus (within 1-2 months), and recall of the message and retention of the recommendation will erode continually thereafter. Therefore, detection of any differences in recommendation compliance among different affective valences should not be affected by a shortened follow-up interval.

Recruitment of student phone interviewers is currently underway and we anticipate initiating the follow-up activities in Month 51 at the earliest or in Month 54 (after the holidays) at the latest. We project that follow-up will take approximately 4-8 weeks.

Finally, we project that data analysis and report preparation will occur in Months 59 and 60.

Key Research Accomplishments

- Production of three, affectively different videotaped stimuli that were developed based on data collected through extensive focus group sessions involving women in the target population.
- Development and testing of pre-/post survey questionnaires.
- Development of training manual and protocol for lay health workers to utilize during the implementation of research in predominantly African American rural communities.

Reportable Outcomes

None

Conclusions

As with most collaborative research studies, unforeseen events occur that are beyond the control of the researchers, and this has been true with regard to the Breast Health Intervention Evaluation Study. However, from a broad perspective, our developmental setbacks have been limited to video production issues and to the survey pre-testing protocol, both of which have been dealt with satisfactorily. Numerous difficulties that we encountered during the implementation phase significantly slowed our progress. Other than a change of one of the location of one of our sites, we have completed the implementation phase according to the Study protocol. We are now embarking upon the follow-up activities, the final phase of this research Study. We foresee no further difficulties in fully completing the Study by 31 July 2001.

References

None

Appendix

None